SPECIALIZED CENTERS OF RESEARCH ON SEX AND GENDER FACTORS AFFECTING WOMEN'S HEALTH

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RFA: RFA-OD-02-002

Office of Research on Women's Health (ORWH)
(http://www4.od.nih.gov/orwh/)
National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS)
(http://www.niams.nih.gov/)
National Institute of Child Health and Human Development (NICHD)
(http://www.nichd.nih.gov/)
National Institute of Dental and Craniofacial Research (NIDCR)
(http://www.nidr.nih.gov/)
National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK)
(http://www.niddk.nih.gov/)
National Institute on Drug Abuse (NIDA)
(http://www.nida.nih.gov/)
National Institute of Environmental Health Sciences (NIEHS)
(http://www.niehs.nih.gov/)
National Institute of Mental Health (NIMH)
(http://www.nimh.nih.gov/)
Food and Drug Administration (FDA)
(http://www.fda.gov/womens/default.htm)

Letter of Intent Receipt Date: February 14, 2002
Application Receipt Date: March 14, 2002

PURPOSE

The Office of Research on Women's Health (ORWH) serves as a focal point for women's health research at the NIH. The ORWH promotes, stimulates, and supports efforts to improve the health of women through biomedical and behavioral research. ORWH works in partnership with the NIH institutes and centers to ensure that women's health research is part of the scientific framework at NIH and throughout the scientific community.

The ORWH now seeks to establish a new program, Specialized Centers of Research on Sex and Gender Factors Affecting Women's Health. These centers will provide new opportunities for interdisciplinary approaches to advancing studies on how sex and gender factors affect women's health. Each SCOR should develop a research agenda bridging basic and clinical research on sex/gender factors underlying a priority health issue. The National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS) will be the service center for the administration of this program.

The ORWH has published "An Agenda for Research on Women's Health for the 21st Century" that provides at outline of research needs identified through national taskforces. The executive summary of this report is available at the following URL:
http://www4.od.nih.gov/orwh/research.html.
This web site also provides the FY 2001 research priorities identified by the Institutes and Centers at NIH working with the ORWH.

HEALTHY PEOPLE 2010

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2010," a PHS-led national activity for setting priority areas. This Request for Applications (RFA), SPECIALIZED CENTERS OF RESEARCH ON SEX AND GENDER FACTORS AFFECTING WOMEN'S HEALTH, is related to one or more of the priority areas. Potential applicants may obtain a copy of "Healthy People 2010" at http://www.health.gov/healthypeople/.

ELIGIBILITY REQUIREMENTS

Applications may be submitted by domestic, for-profit and non-profit organizations, public and private, such as universities, colleges, hospitals, laboratories, units of State and local governments, and eligible agencies of the Federal government. Foreign institutions are not eligible for center grants. Racial/ethnic minority individuals, women, and persons with disabilities are encouraged to apply as Principal Investigators. Established research programs in areas related to the SCOR theme must be present.

MECHANISM OF SUPPORT

This RFA will use the National Institutes of Health (NIH) P50 award mechanism. Responsibility for the planning, direction, and execution of the proposed project will be solely that of the

applicant. The total project period for an application submitted in response to this RFA may not exceed 5 years. This RFA is a one-time solicitation. Future unsolicited competing continuation applications will compete with all investigator-initiated applications and be reviewed according to the customary peer review procedures. The anticipated award date is September 1, 2002.

FUNDS AVAILABLE

The ORWH intends to commit approximately $10 million in FY 2002 to fund 9 - 10 new grants in response to this RFA. An applicant may request a project period of up to 5 years and a budget for direct costs of up to $750,000 in the first year. Although the financial plans of the ORWH provide support for this program, awards pursuant to this RFA are contingent upon the availability of funds and the receipt of a sufficient number of meritorious applications. At this time, it is not known if this RFA will be reissued.

RESEARCH OBJECTIVES

Background

The Office of Research on Women's Health (ORWH) and cosponsors seek to promote interdisciplinary research in sex/gender factors through Specialized Centers of Research (SCOR). Each SCOR will promote interdisciplinary collaborations and develop a research agenda bridging basic and clinical research on sex/gender factors underlying a priority health issue. The SCOR program will complement other Federally supported programs addressing women's health issues. Such programs include the Building Interdisciplinary Research Careers in Women's Health (BIRCWH, see http://www4.od.nih.gov/orwh/bircwhweb.htm), The Women's Reproductive Health Research Career Development Centers (http://www.nih.gov/news/pr/sept99/nichd-13a.htm) and numerous NIH RFAs and PAs (see http://www4.od.nih.gov/orwh/res2.html).

Description of a SCOR

Guidelines have been developed to assist in developing a SCOR application. These guidelines are available at the following URL:
http://www.niams.nih.gov/rtac/grantapps/Guide_pre_grants_app/guide_grant_app.htm#specific

The objective of the SCOR program is to expedite interdisciplinary development and application of new knowledge to human diseases, to learn more about the etiology of these diseases, and to foster improved approaches to treatment and/or prevention.

Each SCOR should have a central theme related to the disease area to which individual projects relate and which serves as an integrating force. The SCOR must provide an interdisciplinary approach utilizing both laboratory and clinical research to focus on a particular health problem and provide for a mutually supportive interaction between basic scientists and clinical investigators. Emphasis in proposed projects should be on interdisciplinary development of innovative approaches, elaboration of new and significant hypotheses, and generation of improved strategies for approaching current issues relating to the disease area addressed. Collaboration among institutions is encouraged within a given SCOR to share scarce patient resources.

A SCOR consists of at least three individual, but interrelated, research projects, each with high scientific merit and clear research objectives and, in the aggregate, devoted to a specific major health area. Both basic and clinical research must be present. An administrative core must be proposed to coordinate the research program, providing intellectual leadership as well as basic management functions. Funding may also be requested for one or more core resources. A core is defined as a resource shared by multiple investigators that enhances research productivity and increases the functional capacity of the SCOR.

NIH defines human clinical research as: (1) Patient-oriented research. Research conducted with human subjects (or on material of human origin such as tissues, specimens and cognitive phenomena) for which an investigator (or colleague) directly interacts with human subjects. Excluded from this definition are in vitro studies that utilize human tissues that cannot be linked to a living individual. Patient-oriented research includes: (a) mechanisms of human disease, (b) therapeutic interventions, (c) clinical trials, or (d) development of new technologies, (2) Epidemiologic and behavioral studies, (3) Outcomes research and health services research.

Support for large clinical trials or for applications that contain exclusively clinical or exclusively basic studies will not be provided within this SCOR program.

Applicants from institutions which have a General Clinical Research Center (GCRC) funded by the NIH National Center for Research Resources may wish to identify the GCRC as a resource for conducting the proposed research. Details of the interactions of the SCOR staff with the GCRC staff and research personnel may be provided in a statement describing the collaborative linkages being developed. A letter of agreement from the GCRC Program Director must be included with the application.

In summary, a SCOR must include a:

1. broad interdisciplinary theme capturing an important issue in sex/gender factors in a priority health issue (See Research Scope, below);

2. Administrative Core with a Center Director, Associate Director and executive committee with outstanding interdisciplinary credentials for advancing the research theme; and

3. minimum of three highly meritorious interdisciplinary research projects, representing both basic and clinical research.

Additional core(s) supportive of two or more of the proposed projects may also be requested.

Research Scope

The research scope for the SCOR program derives from three sources:

1. The Institute of Medicine report, "Exploring the Biological Contributions to Human Health, Does Sex Matter?" defined the use of "sex" and "gender" (p. 8 and 176) as follows. In the study of human subjects, the term "sex" should be used as a classification, generally as male or female, according to the reproductive organs and functions that derive from the chromosomal complement. In the study of human subjects, the term "gender" should be used to refer to a person's self-representation as male or female, or how that person is responded to by social institutions on the basis of the individual's gender presentation. In most studies of nonhuman nimals, the term "sex" should be used. (See http://www.nap.edu and http://www.iom.edu/IOM/IOMHome.nsf/Pages/does+sex+matter+summary).

2. The intellectual background for establishing SCORs in sex/gender factors is also presented in the ORWH publication, "An Agenda for Research on Women's Health for the 21st Century". This outline represents the recommendations from three national topic meetings examining research needs for women's health: (1) Scientific Areas, (2) Sex and Gender Perspectives Throughout the Life Cycle; and (3) Differences Among Populations of Women Throughout the Life Cycle. The executive summary of these outcomes is available at the following URL: http://www4.od.nih.gov/orwh/research.html. The research areas identified through these meetings overlap and the SCOR program will address them through the perspective of sex/gender factors.

3. Current research priorities have been identified by the Institutes and Centers at NIH working with the ORWH and are found at the following URL: http://www4.od.nih.gov/orwh/FY01Respriorities.html. The following research areas are examples of selected priority research areas. They should by no means be viewed as exhaustive, and are intended only as examples of those that may be most amenable to a theme relating to sex/gender factors in women's health:

o Conditions, such as chronic fatigue syndrome, chronic pain, or autoimmune diseases, which may be chronic and/or multi-systemic.

o Influence of toxic environmental factors on women's health. Examples include, but are not limited to, role of gender in biologic response, metabolism and disease patterns resulting from exposure to toxic agents found in the environment, including products used by women; action of environmental estrogenic compounds; biomarkers of exposure and disease in women; gene-environmental interactions, such as environmental exposures, diet, and environmental tobacco smoke, in diseases that particularly impact women; differences in susceptibility to environmental carcinogens; critical exposure windows during sexual development and aging; role of maternal exposure to toxicants in fetal development, disease, and pregnancy outcomes.

o Allergic, immune, and autoimmune diseases, in particular, resistance/susceptibility genes, environmental influences, mechanisms of sex and/or gender factors, immunological mechanisms, target organ influence, role of innate immunity, development of surrogate markers, and immune therapy.

o Neurological diseases, in particular, the influence of sex and/or gender factors, the effect of life events such as pregnancy and menopause on neurological disease, the roles of hormonal, genetic, or environmental factors in etiologies and outcomes of neurological diseases, and development of animal models. Sex and/or gender factors in acute and chronic pain conditions or syndromes, the perception of pain, and analgesic response.

o Kidney disorders including the impact of pregnancy, diabetes, and hypertension on renal function; preeclampsia; causes of altered renal hemodynamics during pregnancy; sex and/or gender factors in renal transplantation, dialysis, and acute renal failure; mechanisms of analgesic nephropathy; effect of hormones and the menstrual cycle on renal function and drug pharmacokinetics; and the effect of collagen vascular diseases on the kidney.

o Urologic and urogynecologic disorders including recurrent and chronic urinary tract infections; vesicoureteral reflux during pregnancy; effect of hormones on bladder function; interstitial cystitis; pelvic floor disorders encompassing genital prolapse and consequent urinary incontinence; sexual dysfunction; impact of bladder physiology of childbirth, exercise, diet, obesity, and hormone deficiency; and outcome measures for surgical, medical, and behavioral treatment of urinary incontinence, bladder dysfunction and pelvic floor disorders..

o Gastrointestinal and digestive health and diseases, including the effect of hormones and the menstrual cycle on the digestive system; irritable bowel syndrome; functional bowel disorders and gut motility.

o Addiction and Mental Health: Biological and behavioral risk factors, including sex and/or gender factors, in the development of mental disorders, including addictive behaviors, schizophrenia, mood, anxiety, and eating disorders. Adverse health consequences of alcohol and tobacco, licit and illicit drug use, addiction, trauma, and abuse, including the role of sex and/or gender factors, and interactions with HIV/AIDS and cancer.

o Pharmacokinetics, pharmacodynamics, and pharmacogenetics, including hormone and drug interaction, in drug-drug interactions, drug-supplement interactions, and in pharmacokinetics and pharmacodynamics during pregnancy.

o Oral health research as related to sex and/or gender factors in disorders of the temporomandibular joint (TMJ) involving orofacial pain and tenderness localized to the masticatory muscles or the TMJ.

o Developmental biology of the vascular system and role of the fetal environment in programming lifelong cardiovascular function. Molecular and physiological mechanisms of hormone action in the cardiovascular system. Cardiovascular complications of diabetes and obesity. Prevention, detection, and management of cardiovascular disease in high-risk populations, such as octogenarian and older women from racial and ethnic minorities. Impact of patient and health care professional behaviors on cardiovascular disease developments and prevention in women.

o Natural history of menopause and its endocrinological, biological, psychosocial, cultural, lifestyle, and environmental determinants, concomitants, and/or sequelae; role of menopause in the chronic diseases of aging; menopause-related pathophysiology; effects of hormone replacement therapy and/or selective estrogen receptor modulators as preventives and their

potential role in cancer etiology; and the development of new strategies, including dietary supplements and complementary and alternative medicine, for alleviating the short-term, clinical problems of the peri- and postmenopausal periods and the prevention of menopause-related diseases of old age.

o Ophthalmic diseases, including dry eye with and without rheumatic disease, macular degeneration, and glaucoma.

SPECIAL REQUIREMENTS

The director and co-director should budget for an annual one day meeting in Bethesda, MD with ORWH staff. The director should be prepared to devote at least 15 percent effort as the director and 20 percent effort as a project PI. Each project and core PI should be prepared to devote at least 20 percent effort.

To be funded, a SCOR must include at least three highly meritorious projects approved for five years. One of these must have the SCOR director as the principal investigator, and the highly meritorious projects must include both basic and clinical research.

Guidelines have been developed to assist in developing a SCOR application. These guidelines are available at the following URL: http://www.niams.nih.gov/rtac/grantapps/Guide_pre_grants_app/guide_grant_app.htm#specific.

INCLUSION OF WOMEN AND MINORITIES IN RESEARCH INVOLVING HUMAN SUBJECTS

It is the policy of the NIH that women and members of minority groups and their sub-populations must be included in all NIH-supported clinical research projects unless a clear and compelling justification is provided indicating that inclusion is inappropriate with respect to the health of the subjects or the purpose of the research. This policy results from the NIH Revitalization Act of 1993 (Section 492B of Public Law 103-43).

All investigators proposing clinical research should read the AMENDMENT "NIH Guidelines for Inclusion of Women and Minorities as Subjects in Clinical Research - Amended, October, 2001," published in the NIH Guide for Grants and Contracts on October 9, 2001 (http://grants.nih.gov/grants/guide/notice-files/NOT-OD-02-001.html); a complete copy of the updated Guidelines are available at http://grants.nih.gov/grants/funding/women_min/guidelines_amended_10_2001.htm.

The amended policy incorporates: the use of an NIH definition of clinical research; updated racial and ethnic categories in compliance with the new OMB standards; clarification of language governing NIH-defined Phase III clinical trials consistent with the new PHS Form 398; and updated roles and responsibilities of NIH staff and the extramural community. The policy continues to require for all NIH-defined Phase III clinical trials that: a) all applications or proposals and/or protocols must provide a description of plans to conduct analyses, as appropriate, to address differences by sex/gender and/or racial/ethnic groups, including subgroups if applicable; and b) investigators must report annual accrual and progress in conducting analyses, as appropriate, by sex/gender and/or racial/ethnic group differences.

INCLUSION OF CHILDREN AS PARTICIPANTS IN RESEARCH INVOLVING HUMAN SUBJECTS

It is the policy of NIH that children (i.e., individuals under the age of 21) must be included in all human subjects research, conducted or supported by the NIH, unless there are scientific and ethical reasons not to include them. This policy applies to all initial (Type 1) applications submitted for receipt dates after October 1, 1998.

All investigators proposing research involving human subjects should read the "NIH Policy and Guidelines" on the Inclusion of Children as Participants in Research Involving Human Subjects that was published in the NIH Guide for Grants and Contracts, March 6, 1998, and is available at the following URL address: http://grants.nih.gov/grants/guide/notice-files/not98-024.html.

Investigators also may obtain a copy of this policy from the program staff listed under INQUIRIES. Program staff may also provide additional relevant information concerning the policy.

REQUIRED EDUCATION ON THE PROTECTION OF HUMAN SUBJECT PARTICIPANTS

NIH policy requires education on the protection of human subject participants for all investigators submitting NIH proposals for research involving human subjects. This policy announcement is found in the NIH Guide for Grants and Contracts Announcement dated June 5, 2000, at the following website: http://grants.nih.gov/grants/guide/notice-files/NOT-OD-00-039.html.

URLS IN NIH GRANT APPLICATIONS OR APPENDICES

All applications and proposals for NIH funding must be self-contained within specified page limitations. Unless otherwise specified in an NIH solicitation, internet addresses (URLs) should not be used to provide information necessary to the review because reviewers are under no obligation to view the Internet sites. Reviewers are cautioned that their anonymity may be compromised when they directly access an Internet site.

PUBLIC ACCESS TO RESEARCH DATA THROUGH THE FREEDOM OF INFORMATION ACT

The Office of Management and Budget (OMB) Circular A-110 has been revised to provide public access to research data through the Freedom of Information Act (FOIA) under some circumstances. Data that are (1) first produced in a project that is supported in whole or in part with Federal funds and (2) cited publicly and officially by a Federal agency in support of an action that has the force and effect of law (i.e., a regulation) may be accessed through FOIA. It is important for applicants to understand the basic scope of this amendment. NIH has provided guidance at: http://grants.nih.gov/grants/policy/a110/a110_guidance_dec1999.htm.

Applicants may wish to place data collected under this RFA in a public archive, which can provide protections for the data and manage the distribution for an indefinite period of time. If so, the application should include a description of the archiving plan in the study design and include information about this in the budget justification section of the application. In addition, applicants should think about how to structure informed consent statements and other human subjects procedures given the potential for wider use of data collected under this award.

LETTER OF INTENT

Prospective applicants are asked to submit a letter of intent that includes a descriptive title of the proposed research, the name, address, and telephone number of the Principal Investigator, the identities of other key personnel and participating institutions, and the number and title of the RFA in response to which the application may be submitted. Although a letter of intent is not required, is not binding, and does not enter into the review of a subsequent application, the information that it contains allows IC staff to estimate the potential review workload and plan the review.

The letter of intent is to be sent to Dr. Julia Freeman by February 14, 2002.

APPLICATION PROCEDURES

The PHS 398 research grant application instructions and forms (rev. 5/2001) at http://grants.nih.gov/grants/funding/phs398/phs398.html must be used in applying for these grants. This version of the PHS 398 is available in an interactive, searchable format. For further assistance contact GrantsInfo, Telephone 301/435-0714, Email: GrantsInfo@nih.gov.

SPECIFIC INSTRUCTIONS

Guidelines have been developed to assist in developing a SCOR application. These guidelines are available at the following URL: http://www.niams.nih.gov/rtac/grantapps/Guide_pre_grants_app/guide_grant_app.htm#specific.

The RFA label available in the PHS 398 (rev. 5/2001) application form must be affixed to the bottom of the face page of the application. Type the RFA number on the label. Failure to use this label could result in delayed processing of the application such that it may not reach the review committee in time for review. In addition, the RFA title and number must be typed on line 2 of the face page of the application form and the YES box must be marked. The RFA label is also available at: http://grants.nih.gov/grants/funding/phs398/label-bk.pdf.

Submit a signed, typewritten original of the application, including the Checklist, and three signed, photocopies, in one package to:

CENTER FOR SCIENTIFIC REVIEW
NATIONAL INSTITUTES OF HEALTH
6701 ROCKLEDGE DRIVE, ROOM 1040, MSC 7710
BETHESDA, MD 20892-7710
BETHESDA, MD 20817 (for express/courier service)

At the time of submission, two additional copies of the application must be sent to:

Dr. Tommy L. Broadwater
Chief, Review Branch
National Institute of Arthritis and Musculoskeletal and Skin Diseases
Natcher Building, Room 5AS.25U - MSC 6500
Bethesda, MD 20892-6500
Bethesda, MD 20814 (for express/courier service)

Applications must be received by March 14, 2002. If an application is received after that date, it will be returned to the applicant without review.

The Center for Scientific Review (CSR) will not accept any application in response to this RFA that is essentially the same as one currently pending initial review, unless the applicant withdraws the pending application. The CSR will not accept any application that is essentially the same as one already reviewed. This does not preclude the submission of substantial revisions of applications already reviewed, but such applications must include an Introduction addressing the previous critique.

REVIEW CONSIDERATIONS

Upon receipt, applications will be reviewed for completeness by the CSR and responsiveness by the NIAMS. Incomplete and/or non-responsive applications will be returned to the applicant without further consideration.

Applications that are complete and responsive to the RFA will be evaluated for scientific and technical merit by an appropriate peer review group convened by the NIAMS in accordance with the review criteria stated below. As part of the initial merit review, all applications will receive a written critique and undergo a process in which only those applications deemed to have the highest scientific merit, generally the top half of the applications under review, will be discussed, assigned a priority score, and receive a second level review by the National Arthritis and Musculoskeletal and Skin Diseases Advisory Council.

Site visits will not be made.

Review Criteria

The goals of NIH-supported research are to advance our understanding of biological systems, improve the control of disease, and enhance health. In the written comments reviewers will be asked to discuss the following aspects of the application in order to judge the likelihood that the proposed research will have a substantial impact on the pursuit of these goals. Each of these criteria will be addressed and considered in assigning the overall score, weighting them as appropriate for each application. Note that the application does not need to be strong in all categories to be judged likely to have major scientific impact and thus deserve a high priority score. For example, an investigator may propose to carry out important work that by its nature is not innovative but is essential to move a field forward.

Review Criteria

Major factors to be considered in evaluation of applications will include:

1. How the proposed SCOR combines basic and clinical research into the scientific goals and research theme;

2. If a competing continuation application, the quality and significance of the progress made in the previous funding period;

3. Scientific merit of each proposed project. [Each project will receive a priority score. This score reflects not only the feasibility of the project and adequacy of the experimental design, but also the design of the project to advance both the theme of the SCOR and the interaction between basic research and clinical investigation];

4. Scientific merit of combining the component parts into a SCOR;

5. Technical merit and justification of each core unit;

6. Competence of the investigators to accomplish the proposed research goals, their commitment, and the time they will devote to the research program;

7. Adequacy of facilities to perform the proposed research, including laboratory and clinical facilities, instrumentation, and data management systems, when needed;

8. Adequacy of plans for interaction among investigators, and the integration of the various projects and core units;

9. Qualifications, experience and commitment of the SCOR Director and his/her ability to devote time and effort to provide effective leadership;

10. Scientific and administrative structure, including internal and external procedures for monitoring and evaluating the proposed research and for providing ongoing quality control and scientific review;

11. Institutional commitment to the program, and the appropriateness of resources and policies for the administration of a SCOR;

12. Adequacy of plans to include both genders and minorities and their subgroups and children as appropriate for the scientific goals of the research. Plans for the recruitment and retention of subjects will also be evaluated.

AWARD CRITERIA

Award criteria that will be used to make award decisions include:

o Scientific merit (as determined by peer review). The primary factors determining the award will be the priority score, the overall balance of meritorious projects (clinical and basic research) within the application relative to the disease area. Since the ORWH is interested in funding only the best research, individual projects or cores of lesser quality may not be funded, even if approved, under the "umbrella" of the SCOR mechanism.
o Availability of funds.
o Programmatic priorities.

Schedule

Letter of Intent Receipt Date: February 14, 2002
Application Receipt Date: March 14, 2002
Peer Review Date: April/May 2002
Council Review: September 2002
Earliest Anticipated Start Date: September 2002

INQUIRIES

Inquiries concerning this RFA are encouraged. The opportunity to clarify any issues or answer questions from potential applicants is welcome.

Direct inquiries regarding programmatic issues to:

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Centers Program, EP
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Bethesda, MD 20892-6500

Bethesda, MD 20814 (for express/courier service)
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FAX: (301) 480-4543
Email: Julia_B_Freeman@nih.gov

Copies of the guidelines for the ORWH SCOR on Sex and Gender Factors Affecting Women's Health may be obtained from the internet at the following site: http://www.niams.nih.gov/rtac/grantapps/Guide_pre_grants_app/guide_grant_app.htm#specific.

Contact information for program staff in participating Institutes:

Estella Parrott, M.D., M.P.H.
Program Director, Reproductive Medicine Gynecology
Reproductive Sciences Branch, Center for Population Research
National Institute of Child Health and Human Development (NICHD)
6100 Executive Boulevard, Room 8B01
Bethesda, MD 20892-7510
Telephone: (301) 496-6515
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Email: ep61h@nih.gov

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Susan F. Wood, PhD
Director, Office of Women's Health
Food and Drug Administration (FDA)
5600 Fishers Lane, HF-8

Rockville, MD 20857
Telephone: (301) 827-0350
Fax: (301) 827-0926
Email: swood1@oc.fda.gov

Direct inquiries regarding fiscal matters to:

Melinda Nelson
Chief Grants Management Officer, Extramural Program
National Institute of Arthritis and Musculoskeletal and Skin Diseases
Natcher Building Room 5AS.49F - MSC 6500
Bethesda, MD 20892-6500
Telephone: (301) 594-3535
FAX: (301) 480-5450
Email: nelsonm@exchange.nih.gov

AUTHORITY AND REGULATIONS

This program is described in the Catalog of Federal Domestic Assistance No. 93.121(NIH). Awards are made under authorization of Title III, Section 301 of the Public Health Service Act (Public Law 78-410, as amended by Public Law 99-158, 42 USC 241). The Code of Federal Regulations, Title 42 Part 52, and Title 45 Part 74, are applicable to this program. This program is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review.

The PHS strongly encourages all grant recipients to provide a smoke-free workplace and promote the non-use of all tobacco products. In addition, Public Law 103-227, the Pro-Children Act of 1994, prohibits smoking in certain facilities (or in some cases, any portion of a facility) in which regular or routine education, library, day care, health care, or early childhood development services are provided to children. This is consistent with the PHS mission to protect and advance the physical and mental health of the American people.

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